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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,914	08/10/2001	Timothy P. Tully	1314.2004-001	5180

21005 7590 05/07/2003

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EXAMINER

BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/07/2003

9.

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/927,914

Applicant(s)

TULLY ET AL.

Examiner

Mojdeh Bahar

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-106 is/are pending in the application.
- 4a) Of the above claim(s) 2,9,10,12,13,21,22,24-48,59 and 65-93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,11,14-20,23,49-58,60-64 and 94-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Applicant's response to the restriction requirement submitted February 4, 2003 (Paper No. 8) is acknowledged.

Applicant's specie election of stroke as the disorder and PDE inhibitors as the augmenting agent with traverse in Paper No. 8 is acknowledged. Applicant argues that the search for all augmenting agents and disorders would not place an undue burden on the office. Note that the many different classes of augmenting agents set forth on page 18 of the specification have different structures, and are thus classified in many different subclasses of class 514. Note also that each disorder represents a separate field of medical technology. The search for one disease does not encompass the search for a second disease/disorder and the search for all diseases and all augmenting agents is therefore an undue burden on the office. The search is not limited to patent files.

Claims 1, 3-8, 11, 14-20, 23, 49-58, 60-64 and 94-106 are herein examined on the merits in so far as they read on the elected species of PDE inhibitors and stroke.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-8, 11, 14-20, 23, 49-58, 60-64 and 94-106 rejected under 35 U.S.C. 103(a) as being unpatentable over Takayama et al. (USPN 5,817,670), Katzung (Basic and Clinical Pharmacology, page 195, 1995) and Tully et al. (WO 96/11270), in view of Calvanio et al. (Elements of cognitive rehabilitation after right hemisphere stroke in Neurol Clin 1993 Feb., 11 (1): 25-57).

Takayama et al. (USPN 5,817,670) and Katzung together teach that phosphodiesterase inhibitors, known to result in accumulation of cAMP, are known to be useful in a method of treating stroke.

Tully et al. (WO 96/11270) teaches a method of regulating long term memory in an animal comprising inducing of expression of a dCREB2 gene encoding a cAMP responsive activator, see claims in particular.

Takayama et al. (USPN 5,817,670), Katzung (Basic and Clinical Pharmacology, page 195, 1995) and Tully et al. (WO 96/11270) taken together do not teach the training of the stroke patient.

Calvanio et al. (Elements of cognitive rehabilitation after right hemisphere stroke in Neurol Clin 1993 Feb., 11 (1): 25-57) teaches the benefits of training to stroke patients. More specifically Calvanio teaches that by detecting and controlling attentional functioning in specific tasks, learning can be accelerated and produce a higher level of outcome, see for example case 1-3. Calvanio also teaches that training of stroke patients was achieved during multiple sessions.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat stroke patients employing a combination of phosphodiesterase inhibitors and training.

One of ordinary skill in the art would have been motivated to treat stroke patients employing a combination of phosphodiesterase inhibitors and training because both PDE inhibitors and cognitive training are known to be useful in method of treating stroke. One of ordinary skill in the art would have reasonably expected a combination of training and PDE inhibitors to be useful in treating stroke patients.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
April 29, 2003



SREENI PADMANABHAN
PRIMARY EXAMINER

5/2/03